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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,914	09/25/2003	Brian B. Lentrichia	11.025011 US	9190

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,914	LENTRICHIA, BRIAN B.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,14-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,14-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed March 9, 2006 has been entered. Claims 3, 6, 7, 17, 19, and 20 have been amended. Claims 4-5, 8-13, 21 and 25 have been cancelled. Claims 1-3, 6-7, 14-20 and 22-24 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection to the specification; and

b) The rejection of claims 3, 7, 17 and 19-20 under 35 U.S.C. 112, second paragraph.

Response to Arguments

3. Applicant's arguments filed March 9, 2006 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1-3, 6-7, 17, 19-20 and 22-23 under 35 U.S.C. 102(b) as being anticipated by Bruchez et al., (US Patent 6,274,323) is maintained for reasons already of record. The rejection was on the grounds that Bruchez et al., teach a method

for assaying a sample for the presence of a target molecule comprising: providing a liquid sample suspected of comprising the target molecule which is a cell surface molecule; contacting the sample with a filter, said filter comprising a sensor which is an antibody attached thereto, said sensor molecule capable of specifically binding to the target molecule, if present; passing the sample transversely through said filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to the target molecule; recovering the remaining liquid sample; and determining whether the target has bound to the sensor.

Applicants' argue that Bruchez et al., do not teach a filter, wherein said filter comprises an antibody sensor wherein passing the sample transversely through said filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to the target molecule. Applicants' point to Bruchez et al., teaching of apparatuses such as capillaries, hollow fibers, needles, pins and the like as teaching away from the use of a filter and urge that these apparatuses will not enable the instant invention. However the examiner is not asserting that capillaries, hollow fibers, needles, pins and the like are filters. Rather the examiner pointed to the microporous membranes as the filter. Bruchez et al., state that these membranes can be any material such as nitrocellulose, polymeric sheets or solid fibers that include those made of cellulose. Thus, these membranes are the filter and not the other apparatuses, therefore the invention is enabled. Furthermore, Bruchez et al., teach that the semiconductor nanocrystals may also be used in competitive microsphere filter assays, such as competitive latex immunoassays. In this application an antibody is conjugated

to microspheres that are caught on pore filters. A sample is passed through the filter and the immobilized antibodies catch any antigen present. If the sample contains no antigen then the enzyme/antigen will bind to the free sites on the antibody on the filter. Bruchez et al., teach multiple simultaneous detections. The detection takes place on the filter or in the filtrate and the assay may be carried out in a high throughput multiwell environment. Thus, almost any target molecule, analyte, chemical or biological, organic or inorganic may be detected in this manner. Separation is achieved because the reaction is free to pass through a microporous filter in which the pores are a smaller size than the diameter of the microsphere. Thus the pressure controlling microsphere cannot pass through the filter. If a known amount of semiconductor nanocrystals are applied with the analyte sample, allowed to bind for a predetermined time and then passed through the filter, the concentration and presence of the bound target analyte is determined by measuring the level of fluorescence. Clearly, the filter enables the passing of the sample, just as required by the claims. Therefore contrary to applicants arguments Bruchez et al., teach all the limitations of the instant claims and the rejection is maintained.

Claim Rejections - 35 USC § 103

5. The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Bruchez et al., in view of Hurley et al., (US Patent 5,256,571) is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to modify the method of assaying a sample

for the presence of a target molecule as taught by Bruchez et al., to further include using a water-soluble alcohol preserving solution as taught by Hurley et al., because Hurley teach that it is desirable to preserve the cell sample and prevent bacterial growth which may occur because of extended preservation.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Bruchez et al., has been discussed above as teaching, in particular, a filter, wherein said filter comprises an antibody sensor wherein passing the sample transversely through said filter using a pressure-controlling apparatus under conditions that allow the sensor molecule to bind to the target molecule. Therefore, the modification of Bruchez et al., in view of Hurley et al., requires no more than routine skill to incorporate the water-soluble alcohol into the sample, since the prior art teaches the beneficial effects of inhibiting bacterial growth that may affect the sterility of the sample due to preservation. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success, since the prior art teaches that the solution can be used with a wide variety of cell types and allows the cell samples to maintain their integrity and be further analyzed

without any interference from the storage and preservation. Therefore the rejection is maintained contrary to applicants' arguments.

Conclusion

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

May 24, 2006

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